

REMARKS

Currently, claims 15-16 and 18-24 are pending in the present application. Exactly three bases for rejection, each based on 35 U.S.C. § 1, are recited in the action. In the first substantive paragraph at page 3 of the Office Action, the Examiner finds the relationship between the recitation of the identifying step indefinite with the recitation of the compiling a profile step and the comparing the amniotic fluid step. The present claim 15 is amended to overcome any potential indefiniteness. Applicant submits that the claim is substantially definite as currently drafted, however, the accompanying clarification should resolve any potential issue of indefiniteness under § 112, second paragraph. Second, the Examiner finds the recitation of “the control profile” unclear in claims 16 and 18-19. This language is also clarified by the amendments entered here. Finally, the Examiner finds the “identifying step” unclear in claims 21-23. The present amendments clarify all of these issues.

The amended claims clarify the “comparing...” and “identifying...” steps with respect to profile of amniotic fluid specimen measured with the analysis “control profile” -- the amended language satisfies the requirements of § 112, 2nd ¶ to particularly point out and distinctly claim the subject matter of the invention.

Specifically, the individual steps are identified as steps a)-e) and the comparing and identifying steps are specifically recited such that the interrelationship between the two is clear. In particular, the identifying step is clarified to indicate that the identification occurs using the comparing step of step d) and is based on the revelation that a difference in the fluid specimen profile compiled in step c) differs from the control profile. The control profile is also clarified in step e) to have antecedent basis in step b). This amendment also addresses the second point

raised in the first substantive paragraph on page 3 of the Office Action because the “profile of metabolites” and “control profile” are indicated to be compared in accord with step b) and c) wherein it is clear that quantities of each metabolite are at issue. Accordingly, it is not a mere difference in the identity of those profiles that are in fact measured, but rather differences in the quantities of the metabolites that are measured. It is believed that the substantive claim language and the foregoing statement, which will become part of the file history of this application, render this point clear beyond dispute.

Additionally, the indefiniteness in the phrase “the control profile” that the Examiner notes in the second paragraph at page 3 of the Office Action, is also addressed by the revisions to claim 15. Clearly, the control profile in claim 16 refers to the control profile identified in both steps d) and e) of claim 15. Accordingly, this basis for rejection has been traversed.

Finally, the Examiner believes that the identifying step recited in claims 21-23 is indefinite. While the Applicant believes the claim language is sufficiently definite as written, Applicant has amended claim 21 to specify that the presence of the “plurality of abnormality quantities” is the basis for the identification of the presence of Down Syndrome. This fact is clarified by reiterating that the plurality of abnormal quantities of metabolites is “compared to the quantity of each metabolite in the control profile.” This emphasizes the fact that the comparison of quantities can result in an abnormal reading and that the abnormal reading identifies the presence of Down Syndrome.

Each of the grounds of rejection in the Office Action are overcome by the foregoing amendments.

CONCLUSION

By entry of this Amendment, Applicant respectfully submits that all of the Examiner's rejections have been overcome. Additionally, the Examiner is invited to telephone the undersigned representative if the Examiner believes that a telephonic interview would advance this case to allowance.

The Commissioner is authorized to charge any additional fees required by the filing of these papers, and to credit any overpayment to Orrick Herrington & Sutcliffe's Deposit Account No. 150665.

Respectfully submitted,

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